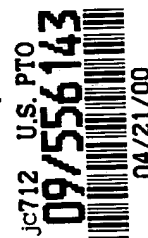


13938-00009

PATENT APPLICATION



TITLE: SEGMENTED SCLERAL BAND FOR TREATMENT OF PRESBYOPIA
AND OTHER EYE DISORDERS

RELATIONSHIP TO OTHER APPLICATIONS

This application is a continuation-in-part of copending application Serial No. 08/462,649, filed June 05, 1995, which is a divisional of U.S. application Serial. No. 08/139,756, filed, October 22, 1993, now U.S. Patent No. 5,489,299, which is a divisional of U.S. application Serial No. 07/913,486, filed July 15, 1992, now U.S. Patent No. 5,354,331.

BACKGROUND OF THE INVENTION

1. Field of the Invention:

This invention relates to methods of treating presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension and more particularly to methods of treating these diseases by increasing the effective working distance of the ciliary muscle. The invention also relates to increasing the amplitude of accommodation of the eye by increasing the effective working range of the ciliary muscle and to ~~prosthetic devices for achieving such increased amplitude of accommodation.~~

2. Brief Description of the Prior Art:

In order for the human eye to have clear vision of objects at different distances, the effective focal length of the eye must be adjusted to keep the image of the object focused as sharply as possible on the retina. This change in effective focal length is known as accommodation and is accomplished in the eye by varying the shape of the crystalline lens. Generally, in the unaccommodated emmetropic eye the curvature of the lens is such that distant objects are sharply imaged on the retina. In the unaccommodated eye, near objects are not focused sharply on the retina because their images lie behind the retinal surface. In order to visualize a near object clearly, the curvature of the crystalline lens is increased, thereby increasing its refractive power and causing the image of the near object to fall on the retina.

The change in shape of the crystalline lens is accomplished by the action of certain muscles and structures within the eyeball or globe of the eye. The lens is located in the forward part of the eye, immediately behind the pupil.

It has the shape of a classical biconvex optical lens, i.e., it has a generally circular cross section having two convex refracting surfaces, and is located generally on the optical axis of the eye, i.e., a straight line drawn from the center of the cornea to the macula in the retina at the posterior portion of the globe. In the unaccommodated human eye the

~~curvature of the posterior surface of the lens, i.e., the~~
surface adjacent to the vitreous body, is somewhat greater
than that of the anterior surface. The lens is closely
surrounded by a membranous capsule that serves as an
intermediate structure in the support and actuation of the
lens. The lens and its capsule are suspended on the optical
axis behind the pupil by a circular assembly of very many
radially directed elastic fibers, the zonules, which are
attached at their inner ends to the lens capsule and at their
outer ends to the ciliary body, a muscular ring of tissue,
located just within the outer supporting structure of the eye,
the sclera. The ciliary muscle is relaxed in the
unaccommodated eye and therefore assumes its largest diameter.

According to the classical theory of accommodation,
originating with Helmholtz, the relatively large diameter of
the ciliary muscle in this condition causes a tension on the
zonules which in turn pulls radially outward on the lens
capsule, causing the equatorial diameter of the lens to
increase slightly and decreasing the anterior-posterior
dimension of the lens at the optical axis. Thus, the tension
on the lens capsule causes the lens to assume a flattened
state wherein the curvature of the anterior surface, and to
some extent the posterior surface, is less than it would be in
the absence of the tension. In this state the refractive
power of the lens is relatively low and the eye is focused for
~~clear vision of distant objects.~~

~~When the eye is intended to be focused on a near object,~~
the ciliary muscles contract. According to the classical theory, this contraction causes the ciliary muscle to move forward and inward, thereby relaxing the outward pull of the zonules on the equator of the lens capsule. This reduced zonular tension allows the elastic capsule of the lens to contract, causing an increase in the antero-posterior diameter of the lens (i.e., the lens becomes more spherical) resulting in an increase in the optical power of the lens. Because of topographical differences in the thickness of the lens capsule, the central anterior radius of curvature decreases more than the central posterior radius of curvature. This is the accommodated condition of the eye wherein the image of near objects falls sharply on the retina.

Presbyopia is the universal decrease in the amplitude of accommodation that is typically observed in individuals over 40 years of age. In the person having normal vision, i.e., having emmetropic eyes, the ability to focus on near objects is gradually lost, and the individual comes to need glasses for tasks requiring near vision, such as reading.

According to the conventional view the amplitude of accommodation of the aging eye is decreased because of the loss of elasticity of the lens capsule and/or sclerosis of the lens with age. Consequently, even though the radial tension on the zonules is relaxed by contraction of the ciliary muscles, the lens does not assume a greater curvature.

~~According to the conventional view, it is not possible by any~~
treatment to restore the accommodative power to the presbyopic
eye. The loss of elasticity of the lens and capsule is seen
as irreversible, and the only solution to the problems
presented by presbyopia is to use corrective lenses for close
work, or bifocal lenses, if corrective lenses are also
required for distant vision.

Certain rings and/or segments have been used in ocular
surgery for various purposes. Rings and/or segments of
flexible and/or elastic material, attached or prepared in situ
by fastening the ends of strips of the material around the
posterior portion of the globe, posterior to the pars plana
(over the underlying retina), have been used to compress the
sclera in certain posterior regions. Supporting rings of
metal, adapted to fit the contour of the sclera have been used
as temporary supporting structures during surgery on the
globe. However, none of these known devices has been used for
surgical treatment of presbyopia, and none has been adapted to
the special needs of prosthetic devices used in treating
presbyopia.

A scleral band adapted to be fastened to the sclera of
the eye in the region of the ciliary body in order to expand
the sclera in that region and thereby increase the working
distance of the ciliary muscle is described in applicant's
U.S. Patent 5,354,331, the entire disclosure of which is
~~incorporated herein by reference. The scleral band of that~~

~~patent is manufactured as a single unitary device that is~~
placed on the surface of the sclera and fastened thereto,
e.g., by suturing. Although the band is effective,
alternative designs are possible that permit greater
flexibility in installing the scleral band.

Accordingly, a need has continued to exist for a scleral
band for treating presbyopia and other eye disorders that
allows the surgeon the opportunity of other methods of
installing or implanting the band.

SUMMARY OF THE INVENTION

An alternative design for a scleral band that can be
implanted to treat presbyopia and other eye disorders is found
in the band of this invention wherein a scleral band comprises
a plurality of segments that can be assembled on the eye to
form a complete scleral band. The invention also comprises a
method for installing such a segmented band comprising the
steps of forming tunnels in the substance of the sclera in the
region overlying the ciliary body, inserting segments of the
segmented band into the tunnels, and uniting the ends of the
segments to form a unitary scleral band.

Accordingly, it is an object of the invention to provide
a treatment for presbyopia.

A further object is to provide a treatment for presbyopia
by increasing the effective working distance of the ciliary
~~muscle in the presbyopic eye.~~

~~A further object is to provide a treatment for presbyopia by increasing the radial distance between the equator of the crystalline lens and the ciliary body.~~

A further object is to provide a treatment for presbyopia by implanting in the sclera in the region overlying the ciliary body a generally rigid band whereby the sclera is expanded in the region of the ciliary body.

A further object is to provide a segmented scleral band that can be assembled on the eye to provide a generally rigid band.

A further object is to provide a segmented scleral band having segments that can be inserted into tunnels prepared in the substance of the sclera and assembled thereafter to provide a generally rigid band.

A further object is to provide a treatment for hyperopia.

A further object is to provide a treatment for primary open angle glaucoma.

A further object is to provide a treatment for ocular hypertension.

A further object is to provide a treatment for increasing the amplitude of accommodation of the eye.

Further objects of the invention will become apparent from the description of the invention which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

~~Figure 1 illustrates a front elevational view of human~~

~~eye with a scleral expansion band of the invention implanted therein.~~

Figure 2 shows a cross-section of the eye shown in Figure 1 along the line 2-2.

Figure 3 shows an enlarged view of the cross section of Figure 4 in the region indicated by the circle 3.

Figure 4 shows a front elevational view of the segmented scleral band of the invention.

Figure 5 shows a side elevational view of the band.

Figure 6 shows an isometric view of the band.

Figure 7 shows a plan view of a segment of the band.

Figure 8 shows an end view of a band segment as indicated by line 8-8 in Figure 7.

Figure 9 shows an end view of a band segment as indicated by line 9-9 in Figure 7.

Figure 10 shows a cross-sectional view of a band segment along line 10-10 in Figure 7.

Figure 11 shows a cross section of the fused tongue and groove portion of the segmented scleral band along lines 11-11 in Figure 4.

DETAILED DESCRIPTION OF THE INVENTION

AND PREFERRED EMBODIMENTS

This invention is based on a theory of presbyopia different from the classical theory of Helmholtz. Although ~~the scope of the invention is not to be bound or limited by~~

~~the inventor's theory, it is the inventor's view that the~~
presbyopic loss of accommodation is due to decreased working
distance of the ciliary muscle. This theory is described in
more detail in Patent No. 5,354,331, referenced above and
incorporated herein by reference. Consequently, according to
the invention, presbyopia is treated by increasing the
effective working distance of the ciliary muscle. This is
accomplished by increasing the distance between the ciliary
muscle and the lens equator by increasing the diameter of the
sclera in the region of the ciliary body.

According to the invention, the effective working
distance of the ciliary muscle is increased by implanting in
tunnels or pockets surgically formed within the tissue of the
sclera of the eye a plurality of scleral band segments. The
segments are then joined to form a complete scleral expansion
band implanted at least partially within the sclera of the
eye. The completed scleral expansion band is sized to be
slightly larger than the sclera in the region of the ciliary
body. Accordingly, the scleral expansion band exerts an
outward traction on the sclera, thereby expanding it slightly
generally in the plane of the crystalline lens. The scleral
expansion also expands, i.e., increases the diameter, of the
ciliary body which lies immediately inside or beneath the
sclera and is anatomically attached thereto.

The relevant anatomy of the eye for understanding the
~~operation of the scleral expansion band of the invention and~~

~~for locating the scleral pockets may be seen by reference to~~
Figures 1-3. Figure 1 shows an eye 100 provided with a scleral expansion band according to the invention. The outermost layer of the eye 100 comprises the white, tough sclera 102 which encompasses most of the globe and the transparent cornea 104, which constitutes the anterior segment of the outer coat. The circular junction of the cornea and sclera is the limbus 106. Within the globe of the eye, as illustrated in the cross-section of Figure 2, taken along line 2-2 in Figure 1, the crystalline lens 108 is enclosed in a thin membranous capsule and is located immediately posterior to the iris 112, suspended centrally posterior to the pupil 114 on the optical axis of the eye. The lens 108 is suspended by zonules 115 extending between the lens capsule at the equator 110 of the lens 108 and the ciliary body 116. The ciliary body 116 lies just under the sclera 102 (i.e., just inwardly of the sclera 102) and is attached to the inner surface of the sclera 102. As may be seen in Figure 2, the ciliary body 116 lies generally in a plane 130 defined by the equator 110 of the lens 108. The plane 130 can also be extended to intersect the sclera 102 whereby it forms a generally circular intersection located about 2 millimeters posterior to the limbus 106.

According to the invention a generally outwardly directed traction is exerted on the sclera in the region of the ciliary body to expand the sclera 102 in that region. This expansion

~~of the sclera 102 produces a corresponding expansion of the~~
attached ciliary body 116 and moves the ciliary body 116
outwardly away from the equator of the lens 108, generally in
the plane 130 of the equator 110 of the lens 108. The sclera
102 is preferably expanded approximately in the plane of the
equator of the lens 108. However, any expansion of the
sclera 102 in the region of the ciliary body 116, i.e., in the
region or zone of the sclera extending somewhat anterior or
posterior to the plane of the equator 110 of the lens 108 is
within the scope of the invention, provided that such
expansion of the sclera 102 moves the ciliary body 116 away
from the equator 110 of the lens 108. Typically, the
expansion of the sclera will be accomplished in the region or
zone from about 1.5 millimeters anterior to the plane 130 of
the equator of the lens 108 to about 2.5 millimeters posterior
to that plane, i.e., from about 0.5 millimeters to about
4.5 millimeters posterior to the limbus 106. Accordingly, the
scleral pocket or tunnel 120 will be located in that region or
zone of the sclera.

The scleral band 200 of the invention is assembled from a
plurality of segments 202. The assembled band 200, as seen in
Figures 1, 4, 5 and 6, has an anterior rim 226, a posterior
rim 228 and a web structure 230 connecting the two rims. In
order to apply the desired outward traction on the sclera at
the region of the ciliary body, at least a circumferential
~~portion of the band, i.e., either the anterior rim 226, the~~

~~posterior rim 228, or the connecting web structure 230, is~~
designed to have a diameter, when the band is assembled,
slightly greater than the diameter of the sclera at the
location where the band is implanted. Of course, the entire
band may have a size slightly greater than the sclera. The
outward tension on the sclera is applied in the region of the
ciliary body as illustrated in Figures 2, which shows a cross-
section of the eye with the scleral band 200 of the invention
implanted, and in Figure 3, which shows a detail of the cross-
section of the eye as indicated by the dashed circle 3 in
Figure 2. The scleral expansion band 200 is shown within the
scleral tunnel 120, which has a base 126, an outer flap 128,
an anterior margin 122 and a posterior margin 124. The
scleral band 200 within the tunnel or pocket 120 exerts an
outward force on the outer flap 128 of the scleral pocket 120
because the band is generally larger in diameter than the
sclera at the zone where the band is implanted. The outer
flap 128 then transfers the outward traction via its
connection to the rest of the sclera at the anterior margin
122 and posterior margin 124. Thereby, the sclera is expanded
in a zone surrounding the ciliary body 116 and causes the
attached ciliary body 116 to be increased in diameter as well.
Accordingly, the scleral pockets or tunnels 120, which
resemble belt loops through which the scleral expansion band
is threaded, are located in the region of the ciliary body,
~~and generally close to a plane defined by the equator of the~~

~~crystalline lens. Thus, the scleral expansion band is~~
positioned with respect to the antero-posterior axis of the
globe of the eye, such that it will exert a traction on the
sclera that will produce a radial expansion of the ciliary
body located just beneath or within the sclera.

The scleral band and its segments are illustrated in
Figures 4-11 of the drawings wherein the reference numerals
refer to the same parts throughout. The scleral band 200 is
comprised of a plurality of segments 202. The band 200 is
designed to be applied to the sclera of the eye by forming
scleral pockets or tunnels in the sclera, then passing a
segment 202 through each of the tunnels and fastening the ends
of the segments together to form a complete band.

Accordingly, each segment 202, as shown in Figures 9-10,
has an anterior edge 204, a posterior edge 206, an outer
surface 208, an inner surface 210, and two lateral ends 212
and 214. Although the illustrated embodiment of the segment
shows a continuous web 230 of material connecting the anterior
edge 204 and the posterior edge 206, the connecting structure
230 need not be such a continuous structure. Any structure,
e.g., a web having apertures, or a lattice structure, is
suitable, provided that the connecting structure has
sufficient strength to keep the anterior edge 204 and the
posterior edge 206 in their relative positions to provide the
necessary rigidity to the assembled band 200. In the
~~illustrated embodiment, one lateral end 212 of each segment~~

~~202~~ is provided with a tongue 216, and the other lateral end 214 is provided with a corresponding groove 218. After the segments are inserted through the scleral tunnels, the ends 212 and 214 are exposed as shown in Figure 1. Each tongue 216 is then inserted into its corresponding groove 218, and the tongues 214 are then fastened in place within the grooves 218 to form the complete scleral band as shown in Figures 1, 4, and 5. Any means of fastening the segments 202 together is suitable. The segments may be bonded with an adhesive or welded or fused together, or a mechanical fastener, such as a screw or rivet can be used to fasten the ends of the segments 202 together. A preferred method of fastening the segments 202 together, when the segments are made from a preferred plastic material such as poly(methyl methacrylate) is to weld or fuse the lower surface 218 of the tongue 216 to the bottom 222 of the groove 220 by ultrasonic welding. The ultrasonic welding can be accomplished by conventional techniques. For example, the tongue 216 can first be positioned in the groove 220, then a support shoe is inserted under the end 214 of the segment 202 and an ultrasonic welding tool is applied to the tongue 216 for a time sufficient to form a fused welded area 224 (Figure 11).

The segments 202 are typically dimensioned to fit snugly in the scleral tunnels. A typical segment will have a width of about 2 millimeters and a thickness of about 0.25 millimeters. The length of a typical segment, measured

~~along the circumference from one end of the main body of the~~
segment 202 to the other will be about 13 millimeters. The
tongue will be about 3 millimeters in length. The skilled
practitioner will understand that the dimensions will be
adapted to the particular eye into which the scleral band is
to be implanted. In particular, an assortment of lengths is
typically made available to the surgeon so that segments can
be selected that, when assembled on the globe of the eye, the
completed scleral expansion band will be of the proper size to
exert the desired outward traction on the sclera and ciliary
body. If the segments 202 are made of a material that has
some flexibility perpendicular to the surface thereof, e.g., a
synthetic resin material, the segments can be made flat and
curved to match the curvature of the globe of the eye when the
band is implanted. If the band is made of a more rigid
material it is preferable to form an appropriate curve before
insertion. A typical segment of the preferred embodiment as
illustrated will have a radius of curvature of the anterior
rim of about 8.3 millimeters, and a corresponding radius of
curvature of the posterior rim of about 10.3 millimeters. The
radii of the rims can be accommodated to the particular
dimensions of the eye into which the band is to be implanted.

Although the illustrated embodiment shows a tongue-and-groove design for joining the segments 202 that form the scleral band 200, the skilled practitioner will understand that other designs can be used as well. For example a simple

~~butt joint effected by adhesive joining or welding could be~~
used. Similarly, a lap joint or a tapered scarf joint can be
used. Again one end of the segment 202 can be provided with a
projection that fits into a recess or hole in end of the
adjacent segment. The ends can be shaped to have
complementary shapes that fit together much as a pieces of a
jigsaw puzzle.

In practicing the method of the invention, the surgeon
first locates the proper region or segment or zone of the
sclera to be expanded by measuring a distance of preferably
2.0 millimeters posterior of the limbus. The scleral tunnels
or pockets are then formed, preferably by the following
procedure. At 2.5 millimeters clockwise and counterclockwise
from each of the 45° meridians of the eye, and 2 millimeters
posterior to the limbus, partial scleral thickness radial
incisions, i.e., antero-posterior incisions, are made which
are 2 millimeters long and 350 microns deep. Using a lamella
blade the sclera is dissected until the partial thickness
incisions are connected so that four scleral pockets or belt
loops are made which have an anterior length of 5 millimeters,
and a length extending generally axially of the eye of
2 millimeters. Thus, each pocket or belt loop is preferably
centered over the 45° meridian of the eye. Each tunnel is
directed generally circumferentially with respect to a circle
defined generally by the intersection of the sclera with the
~~plane of the equator of the crystalline lens, although the~~

~~tunnels need not be exactly in that plane. A segment 202 of~~
the scleral band 200 is then inserted in each pocket so that
the ends 212 and 214 of the segments 202 meet in the spaces
between the pockets, as shown in Figure 1. The ends 212 and
214 of the segments 202 are then joined. In the illustrated
embodiment the ends are joined by fitting the tongue 216 of
one segment 202 into the groove 220 of the adjacent segment
and fastening the tongue in the groove by ultrasonic welding
or other joining technique as discussed above. The completed
scleral band then produces symmetrical scleral expansion which
will produce the desired result of increasing the effective
working distance of the ciliary muscle.

The illustrated embodiment of the invention illustrates a
preferred embodiment of the invention using use of four
scleral tunnels and four scleral band segments. Fewer or more
tunnels may be used at the surgeon's choice. It is not
excluded that a single tunnel could be used with the segments
of the band being joined through appropriate incisions.

The scleral band of the invention is made of a material
that is sufficiently rigid to exert a force on the sclera
sufficient to produce the radial expansion required by the
method of the invention and that is physiologically acceptable
for long-term implantation or contact with the ocular tissues.

Such materials are well-known in the surgical art and include
suitable metals, ceramics, and synthetic resins. Suitable
~~metals include titanium, gold, platinum, stainless steel,~~

~~tantalum, shape-memory alloys, and various surgically~~
acceptable alloys, and the like. Suitable ceramics may include crystalline and vitreous materials such as porcelain, alumina, silica, silicon carbide, high-strength glasses and the like. Suitable synthetic materials include physiologically inert materials such as poly(methyl methacrylate), polyethylene, polypropylene, poly(tetrafluoroethylene), polycarbonate, silicone resins and the like.

The segment may also be made of composite materials incorporating a synthetic resin or other matrix reinforced with fibers of high strength material such as glass fibers, boron fibers or the like. Thus, the segment may be made of glass-fiber-reinforced epoxy resin, carbon fiber-reinforced epoxy resin, carbon fiber-reinforced carbon (carbon-carbon), or the like. A preferred material for the segment 202 is surgical grade poly(methyl methacrylate).

The segment of the scleral band of the invention may be manufactured by any conventional technique appropriate to the material used, such as machining, injection molding, heat molding, compression molding and the like.

The use of the scleral band of the invention to expand the sclera in the region of the ciliary body and increase the working distance of the ciliary muscle may also be of benefit in treatment of hyperopia in certain patients. Some youthful hyperopes can achieve relatively normal vision by compensating ~~for their hyperopia through the natural accommodative ability~~

~~of the eye. However, as this ability declines with age, they~~
find that it becomes more difficult to attain normal vision by
this process, and they begin to experience headaches and other
symptoms, even at an age somewhat less than usual for the
onset of presbyopia. Evidently, increasing the amplitude of
accommodation by the method of this invention would be useful
in restoring the ability of these patients to compensate for
their hyperopia.

The method of this invention also has utility in the
treatment of primary open-angle glaucoma, which shows a
correlation with age in certain individuals. It has been
found that, in general, intraocular pressure (IOP) exhibits a
linear increase with increasing age. (Armaly, M.F., On the
distribution of applanation pressure I. Statistical features
and the effect of age, sex, and family history of glaucoma,
Archives of Ophthalmology, Vol. 73, pp. 11-18 (1965)). Among
the general population is found a group of individuals who
develop abnormally high intraocular pressures as a result of
primary open angle glaucoma, a disease which is one of the
most prevalent causes of blindness in the world. According to
the theory of this invention, the linear increase in IOP with
age is a direct result of the decrease in distance between the
lens equator and the ciliary muscle and the resulting linear
decrease in the effective pull of the ciliary muscle. Since
the ciliary muscle inserts into the trabecular meshwork, the
~~decrease in pull will decrease the size of the trabeculum~~

~~and/or the drainage pores and result in a linear increase of~~
intraocular pressure with age. In this view, the patients who develop primary open angle glaucoma may have a congenital predilection to narrower pores, protein deposition in the pores, and/or a smaller trabecular meshwork, so that when the ability of the ciliary muscle to exert force declines, after the age of 40 or thereabouts, they tend to develop excessively elevated IOP.

The use of the scleral band of the invention to increase the effective working distance of the ciliary muscle, and thereby increase the force that it can exert when it contracts, restores the level of force which the ciliary muscle exerts on the trabecular meshwork to a value characteristic of a more youthful eye. In this way it is expected that the tendency of an eye that is disposed to develop primary open angle glaucoma as it ages would be overcome and the onset of this disease would be prevented or at least postponed.

The invention having now been fully described, it should be understood that it may be embodied in other specific forms or variations without departing from its spirit or essential characteristics. Accordingly, the embodiments described above are to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the ~~appended claims rather than the foregoing description, and all~~

~~changes which come within the meaning and range of equivalency
of the claims are intended to be embraced therein.~~